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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/206,329 12/08/98 ZHANG

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EXAMINER

QM12/0317

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ART UNIT	PAPER NUMBER

3737

DATE MAILED:

03/17/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/206329

Applicant(s)

Examiner

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 2/14/00

☒ This action is **FINAL**.

- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-36 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, "that together" is vague. Does this mean that they are connected to each other, or operate simultaneously, or in harmony with each other?

In claims 23 and 30, "the pacing and sensing means" lacks antecedent basis.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 4, 11, 12, 14, 15, 19, 20, 22, 29, 30, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvian (4991583). For claim 19, the use of “capacitors that together” is a broad term that does not have to mean “connected together” but could mean that they act simultaneously, or in harmony, or that they are both used for afterpotential reduction. The system of Silvian shows the use of both capacitors C2 and both capacitors C5 “that together” perform afterpotential reduction.

6. Claims 1, 2, 4, and 8-15, 19, 20, 22, and 26-33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Silvian.

For claims 8-10, 13, 26-28 and 31, Figure 4 of Silvian shows the claimed sensing means as the “ECG amplifier” capable of sensing the evoked response using any electrode configuration.

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In the alternative, for claims 8-10, 13, 26-28 and 31, Silvian discloses the claimed invention except for sensing the evoked response between a ventricular and an atrial electrode (tip or ring). It would have been obvious to one having ordinary skill in the art at the time the invention was made to sense evoked responses between a ventricular electrode and an atrial electrode since it was known in the art that sensing between a ventricular electrode to an atrial electrode is used to sense evoked responses in the heart and for detecting arrhythmias, conduction times, and heart beats.

7. Claims 1, 2, 16-20, and 34-36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Zhu et al (5843136).

8. Claims 1, 2, 16-20 and 34-36 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The subject matter in the application is the same subject matter in the Zhu et al patent (5843136), but the inventive entity is different.

9. Claims 3, 5-7, 21, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvian.

Silvian discloses the claimed invention except for sensing the evoked response between an atrial or ventricular electrode (tip or ring) to an indifferent electrode positioned on a can of the pacer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to sense between an atrial or ventricular electrode to an indifferent electrode positioned on a can of the pacer (instead of the case of the pacer) since it was known in the art that sensing between an atrial or ventricular electrode to an indifferent electrode positioned on a can of the

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pacemaker is used to provide unipolar sensing of evoked responses of the heart and is used for detection of particular heart conditions of a patient.

10. Claims 3-15 and 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al.

Zhu et al discloses the claimed invention except for the unipolar or bipolar sensing between atrial electrodes, ventricular electrodes, and case/can electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have unipolar or bipolar sensing between atrial electrodes, ventricular electrodes, and case/can electrodes since it was known in the art that unipolar or bipolar sensing between atrial electrodes, ventricular electrodes, and case/can electrodes is used in pacers to sense heart activity and the particular configuration is chosen depending on implantation and sensing of particular heart conditions.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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12. Claims 1-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5843136. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a unipolar or bipolar sensing system in the pacing system to sense, by unipolar or bipolar sensing, evoked responses from the heart using a combination of atrial electrodes, ventricular electrodes or can/case electrodes.

Response to Arguments

13. Applicant's arguments filed 2/14/00 have been fully considered but they are not persuasive.

The addition to the claims of the limitation "said sensing means including multiple independent blanking switches corresponding to independent electrodes" is still met by the Silvan (figures 1, 3, and 4) and the Zhu (figure 3) references since they both contain multiple independent switches, connected to independent electrodes, that can be operated or used ("blanking") during different periods before and after applying a pulse to remove afterpotential. The limitation does not state what the switches are used for, just that they are "blanking" switches.

Silvan does disclose the claimed limitations using both capacitors C2 and/or both capacitors C5 for the afterpotential reduction. Although the applicant states that "the attenuation means or coupling capacitors having reduced capacitance is not shown or described in Silvan", it

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is noted that the claims do not contain a limitation to the attenuation means or coupling capacitors "having reduced capacitance". The 102/103 rejection is also used for Silvian since claims 8-10, 13, 26-28 and 31, are met by the ECG amplifier shown in figure 4.

It is noted that the 102 (e) and (f) rejections still apply to Zhu et al.(5843136). The rejection is given since the application is claiming the same subject matter as disclosed in the patent, but the inventive entity is different.

For the 103 and double patenting rejections, the examiner has taken the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a unipolar or bipolar sensing system in the pacing system to sense, by unipolar or bipolar sensing, evoked responses from the heart using a combination of atrial electrodes, ventricular electrodes or can/case electrodes. In addition, the inclusion of sensing between different atrial/ventricular/case/can electrodes provides sensing of evoked responses in the heart and provides for detecting arrhythmias, conduction times, and heart beat, or is used in pacers to sense heart activity, or the particular sensing configuration is chosen depending on implantation and sensing of particular heart conditions, or is used for detection of particular heart conditions of a patient or for unipolar sensing of evoked responses of the heart. In each case, the motivation or suggestion to combine is provided, such as "to sense evoked responses" or "for detection of particular heart conditions" or "for detecting arrhythmias, conduction times, and heart beats". As an example of one teaching showing that it is known in the art to sense between different electrodes, the Sholder reference, 5222493, was initially provided.

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In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Evanisko whose telephone number is (703) 308-2612.

GRE

March 16, 2000


George R. Evanisko
Patent Examiner